PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-380-6738

Date of Study: December 2023 to April 2025

Short Study Title: Study of B/F/TAF in Participants Switching from CAB + RPV to B/F/TAF for HIV-1 Infection

Study Nickname: EMPOWER

Date of this Plain Language Summary: December 2025

The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who took part in the clinical study for **B/F/TAF**, also known as **bictegravir/emtricitabine/tenofovir alafenamide**, brand name: **Biktarvy**.

Gilead Sciences sponsored this study. This summary is prepared for study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or healthcare provider before making any treatment changes.

This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

General information of the study

What is HIV?

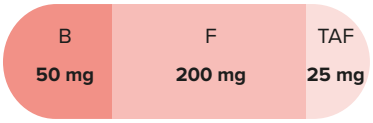
Human immunodeficiency virus (HIV) attacks the body's immune system and makes it more likely for people to get sick. HIV-1 is a type of HIV. There is currently no cure for HIV-1, once someone gets it, they have it for life unless researchers find a cure. However, HIV-1 can be managed with proper treatment.

People living with HIV-1 often take injections or combinations of pills (tablets), to keep HIV-1 under control. Cabotegravir + Rilpivirine (CAB + RPV) combination of injections is an approved treatment for HIV-1. These are long-acting injections and need to be taken only once every 1 or 2 months. Although many people prefer long-acting HIV treatments, CAB + RPV injections can sometimes be challenging to maintain.

Doctors often observe that people starting CAB + RPV do not stay on the injections for long. This is due to various reasons—struggling to stick to the schedule, missing appointments (e.g., due to vacations), side effects, or the burden of frequent injections or clinic visits. Reports show up to 20% of people starting CAB + RPV switch back to daily tablets.

In this study, the researchers wanted to find out if people with **virologically suppressed** HIV-1 who were receiving CAB + RPV injections could benefit from switching to B/F/TAF tablet taken by mouth (oral tablet). **Virologically suppressed** means the virus levels are not delectable in the blood—HIV-1 is under control. B/F/TAF is a single tablet that combines 3 medicines—bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF). It is an approved medicine for HIV-1 treatment.

B/F/TAF Tablet



This was a **Phase 4** clinical study, which means, the researchers were gathering more information about the safety, benefits, and best way to switch from CAB + RPV injections to B/F/TAF tablets.

What was the purpose of the study?

The main purpose of this study was to learn more about the safety of switching from CAB + RPV injections to B/F/TAF tablets during the first 12 weeks of treatment. This was done in people living with virologically suppressed HIV-1 who were either unable or unwilling to continue CAB + RPV injections and wished to switch to the oral therapy.

The main questions the researchers wanted to answer in this study were:

During this first 12 weeks of switching to B/F/TAF treatment:

- **How many participants had severe or potentially life threatening abnormalities in their laboratory test results?**
  Laboratory abnormalities were the laboratory test results that were out of the normal reference range.
- **How many participants had severe or potentially life threatening side effects?**
  Unwanted medical events can happen to the study participants when they take a study drug. In this summary, "**side effects**" are defined as unwanted medical events that the study doctors thought might be caused by the study drug.

- **Severe:** Inability to perform usual activities, with need to be on medication or hospitalisation.
- **Potentially life-threatening:** Inability to do self-care—needing urgent care, medications or hospitalisation to prevent permanent impairment, disability or death.

Researchers also wanted to know about the **overall side effects** that participants had during the study.

Who took part in the study?

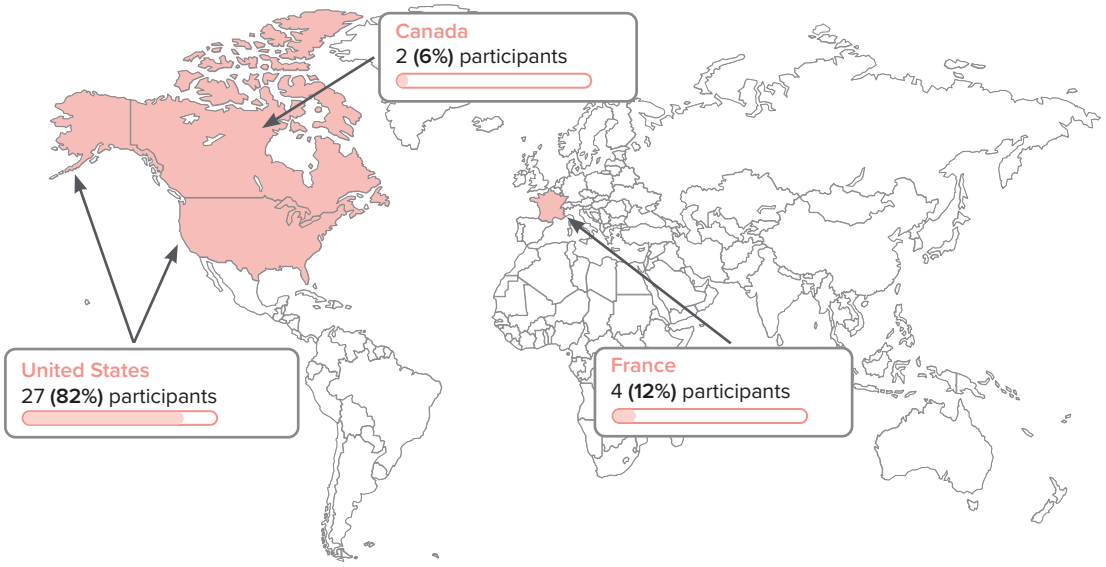
33 adults living with in active HIV-1 in **Canada**, **France** and the **United States** took part in the study.

People could take part in the study if they:

- Were 18 years of age
- Had laboratory confirmed virologically suppressed HIV-1 infection
- Took at least 1 injection of CAB + RPV in the past and were willing to switch to the oral therapy
- Did not have any tolerance issues for B/F/TAF in the past

The study participants were between the ages of **20** and **72** years.

The participants from each country are shown below (Number (%) of participants).



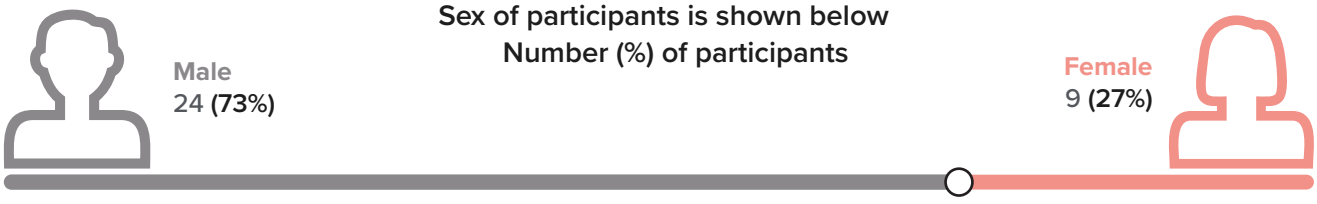
The race of participants is shown below (Number (%) of participants).

White	18 **(55%)**
Black or African American	6 **(18%)**
Not Collected	4 **(12%)**
Other or More Than One Race	2 **(6%)**
American Indian or Alaska Native	1 **(3%)**
Asian	1 **(3%)**
Native Hawaiian or Other Pacific Islander	1 **(3%)**

The ethnicity of participants is shown below (Number (%) of participants).

Not Hispanic or Latino	20 **(61%)**
Hispanic or Latino	11 **(33%)**
Not Collected	2 **(6%)**

Sex of participants is shown below
Number (%) of participants



What happened during the study?

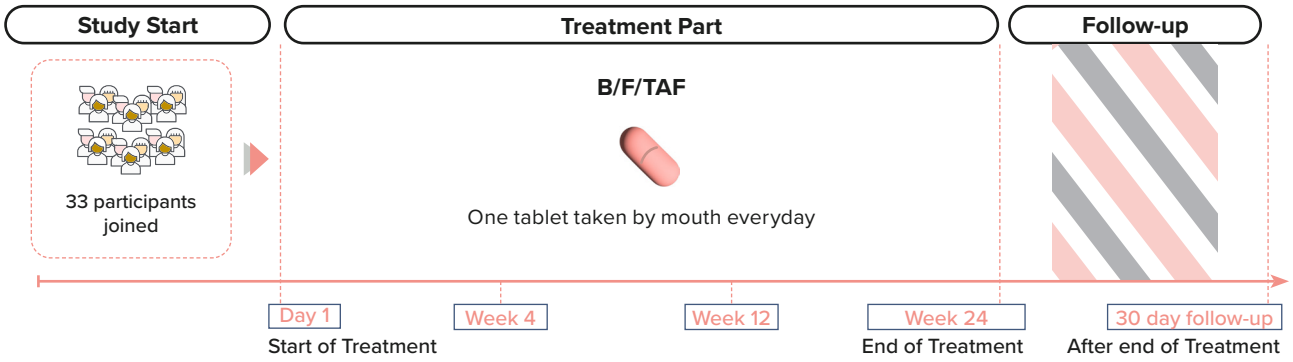
This was an **open-label**, **single arm** study.

Open-label means the participants, doctors, and study staff knew that each participant was taking B/F/TAF.

Single arm means all participants took the same drug, B/F/TAF.

All participants in this study took one B/F/TAF tablet by mouth every day for about 24 weeks.

The graphic below show the treatment plan.



Participants had clinic visits during the study. During these visits, the study doctors took blood and urine samples to check if participants had any changes in their laboratory test values. They also checked participants for any medical events and other health problems.

When the study closed, 29 out of 33 participants completed the study. Four participants discontinued: 2 participants lost contact, 1 participant died and 1 chose to stop participation.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many participants had severe or potentially life threatening abnormalities in their laboratory test results, during the first 12 week of B/F/TAF treatment?

The researchers did laboratory tests and measurements of participants before and after taking the treatment. They checked if participants had laboratory abnormalities. They also assessed if these abnormalities were mild, moderate, severe or potentially life-threatening.

The results are reported for 32 out of 33 participants. These 32 participants had at least one laboratory test measurement after joining the study.

During the first 12 weeks of B/F/TAF treatment, 1 out of 32 (3%) participants had severe or potentially life-threatening laboratory abnormalities.

How many participants had severe or potentially life threatening side effects during the first 12 weeks of B/F/TAF treatment?

The researchers kept track of any side effects that the participants had during the study. Similar to laboratory abnormalities, they assessed if the side effects were mild, moderate, severe or potentially life-threatening.

During the first 12 weeks of B/F/TAF treatment, none of the participants had any severe or potentially life threatening side effects.

What side effects did participants have during the study?

The results from several studies are usually needed to help decide if a study drug actually causes a side effect. The researchers assessed if the side effects were **serious** or non-serious in nature.

A side effect is considered "**serious**" if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

Below is the summary of side effects that participants had during the study:

- There were 7 participants who had side effects in this study
- None of the participants stopped taking B/F/TAF due to any side effects
- **None of the participants had any serious side effect or died due to any serious side effects**

The most common non-serious side effects were **diarrhea (loose watery stools)** and **headache**, each reported by **2 out of 33 (6%)** participants. These side effects were not serious in nature and did not meet the definition of 'serious side effects' mentioned above in this summary.

There were other non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 non-serious side effect.

How has this study helped researchers?

The researchers learned more about the safety of B/F/TAF and how it worked in people living with virologically suppressed HIV-1.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Gilead plans to have real-world evidence (RWE) studies with Biktarvy. These studies use real-world data from everyday medical care to understand how well a treatment works and how safe it is.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
European Medicines Agency www.clinicaltrialsregister.eu	EudraCT Number: 2023-506660-13-00
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov Number: NCT06104306
Gilead Website www.gileadclinicaltrials.com	GS-US-380-6738

Please note that information on these websites may be presented in a different way from this summary.

Full Study Title: A Phase 4 Study to Evaluate the Safety, Pharmacokinetics and Efficacy of Oral B/F/TAF after Discontinuing Injectable CAB + RPV

To learn more about clinical trials in general,
please visit this page on www.clinicaltrials.gov.website

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Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

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